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Before addressing each reference, it is noted that independent Claims 21 and 26 have been amended to incorporate the feature recited in dependent Claims 24 and 28, respectively, i.e., "wherein the cap consists of a material with a modulus of elasticity different from polypropylene" and to delete reference to the phrase "such that some air remains in the package". Accordingly, the arguments asserted below to address the rejection are based on amended independent Claims 21 and 26.

With respect to EP'134, the Examiner states in part:

> EP 0322134 disclosed a method of packaging and steam sterilizing a pharmaceutical product such as saline solution...EP 0322134 further teaches that the lids or caps of the bottles can be formed of other polymeric materials other than polypropylene (see column 3, lines 29-49).

In response, Applicants assert that while EP'134 describes a method of preparing and sterilizing a pharmaceutical package, EP'134 further indicates at column 3, lines 29-49 that while the caps are preferably formed of a polypropylene, other polymeric materials might also be suitable for the bottles and caps. Accordingly, there is no teaching or specific suggestion in EP'134 that the material utilized for the cap consist of a material having a modulus of elasticity different from the material of the polypropylene bottle, or that a squeezable package made from such a combination of cap/bottle can be sterilized as set forth in amended independent Claims 21 and 26.

The Examiner further states:

> Another well-known material used to make pharmaceutical packages is polyethylene and furthermore, high-density polyethylene is known to have a high heat resistance and withstands heat sterilization. Therefore, the use of other materials such as high-density polyethylene would result in a modulus of elasticity that is different than polypropylene.

In response, Applicants assert that the Examiner's statements pertaining to the state of the art of high density polyethylene are not supported by the objective evidence provided by the Examiner, i.e., EP'134 or EP'260 (see discussion of EP'260 below). Applicants reiterate that EP'134 is completely devoid of any teaching or specific suggestion of a method of sterilizing a squeezable package made of a polypropylene bottle and a cap, wherein the cap consists of a material with a modulus of elasticity different from polypropylene as recited in amended independent Claims 21 and 26. Applicants respectfully submit that the Examiner provide an affidavit or declaration setting forth specific factual statements and explanation to support his finding of what is known in the art regarding high density polyethylene and to support the contention that one skilled in the art would have been motivated to combine a cap with a polypropylene bottle, wherein the bottle has a different modulus of elasticity from the cap in a method for sterilization as is set forth in Claims 21 and 26.

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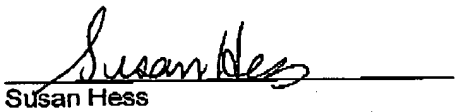
With respect to EP'260, the Examiner acknowledges that the reference specifically describes a flexible pharmaceutical package made of a nylon-polypropylene-polyethylene copolymer laminate sheet that is formed into a tube and a method for sterilizing the tube. EP'260, however, does not teach or specifically suggest a squeezable package made of a polypropylene bottle and a cap, wherein the cap has a different modulus of elasticity from the polypropylene bottle, or that such a combination of bottle/cap can be sterilized by the method as is set forth in amended independent Claims 21 and 26. Thus, EP'260 fails to remedy the deficiencies present in EP'134. Accordingly, the cited references each taken alone or in combination do not make obvious Claims 21-29.

In view of the above, withdrawal of the rejection of Claims 21-29 is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached pages are captioned "Version With Markings To Show Changes Made."

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, he is requested to call the undersigned at the number listed below.

Respectfully submitted,



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Date: July 16, 2003

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Version With Markings To Show Changes Made

The application has been amended as follows:

In the Claims:

Claims 24 and 28 have been cancelled without prejudice.

Claims 21, 25, 26 and 29 have been amended as follows:

21. (Amended) A method for sterilizing a closed squeezable pharmaceutical package wherein the package is selected from the group consisting of a tube comprising a laminated polypropylene foil and a polypropylene bottle with a cap, wherein the cap consists of a material with a modulus of elasticity different from polypropylene, and wherein the pharmaceutical package is suitable for the controlled dispensation of an ophthalmic liquid, ophthalmic gel, or ophthalmic ointment, comprising the steps of:

disposing an amount of a member selected from the group consisting of an ophthalmic liquid, gel, or [ointment] ointment within the package [such that some air remains in the package];

closing the package to yield a closed package;

placing the closed package into an autoclaving chamber; and

increasing temperature and pressure in the chamber until the temperature in the chamber reaches at least 121°C; thereby

avoiding deformation of the package.

25. (Amended) The method of claim [24] 21, wherein the material of the cap is high density polyethylene.

26. (Amended) A method for sterilizing a closed, squeezable pharmaceutical package wherein the package comprises a polypropylene bottle with a cap, wherein the cap consists of a material with a modulus of elasticity different from polypropylene, and wherein the pharmaceutical package is suitable for the controlled dispensation of an ophthalmic liquid and an ophthalmic gel, comprising the steps of:

disposing an amount of a member selected from the group consisting of an ophthalmic liquid and an ophthalmic gel within the package [such that some air remains in the package];

closing the package with the cap to yield a closed package;

placing the closed package into an autoclaving chamber; and

increasing temperature and pressure in the chamber until the temperature in the chamber reaches at least 121°C; thereby avoiding deformation of the package.

29. (Amended) The method of claim [28] 26, wherein the material of the cap is high density polyethylene.